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IN RE APPLICANT : Jackowski et al.

INVENTION : Glycoprotein and Apolipoprotein
Biopolymer Markers Indicative of
Alzheimer's Disease

SERIAL NUMBER : 09/993,344

FILING DATE : November 23, 2001


EXAMINER : Chernyshev, Olga N

GROUP ART UNIT : 1649

OUR FILE NO. : 2132.096

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the attached correspondence is being transmitted to the Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 via facsimile (Fax No. (571) 273-8300) on 2-9-2006


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DECLARATION UNDER 37 CFR § 1.132

I, Ferris H. Lander, do hereby declare as follows:

1. I am a registered Patent Agent and am authorized to represent the inventor's and assignee in the application entitled "Glycoprotein and Apolipoprotein Biopolymer Markers Indicative of Alzheimer's Disease", having U.S. Application Serial No. 09/993,344, filed November 23, 2001.

2. In the Office Action mailed on July 28, 2005, claim 1 (as presented on April 4, 2005) was rejected under 35 USC 101 because the claimed invention allegedly is not supported by either a

McHale & Slavin P.A. 2132.096 -Declaration 37 CFR 1.132 Page 1 of 4

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specific, substantial, credible or asserted utility or a well-established utility. Claim 1 was also rejected under 35 U.S.C. 112, first paragraph because the claimed invention allegedly contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

3. A similar Declaration (to the instant Declaration) with an attached figure (figure attached hereto is identical to that figure filed with the previous Declaration) was previously filed on October 13, 2005 with the Response to the Office Action mailed on July 28, 2005. However, the Examiner found the Declaration to be insufficient since the copy of Figure 1 filed with the Declaration was allegedly of less clarity than the originally filed Figure 1.

Applicants respectfully disagree with the Examiner's assertion. However, the copy of Figure 1 attached to the instant Declaration will also be forwarded by e-mail to the Examiner such that the figure will not be subjected to the PTO scanning system which may obstruct the clarity of the figure.

4. The claimed peptide (amino acid residues 2-18 of SEQ ID NO:1) was obtained from Band C1 of the gel shown in Figure 1. Band C1 is present in lanes 5-8 (as read from the left) which contain samples obtained from patients age-matched with the patients having Alzheimer's disease. However, Band C1 is absent from lanes 1-4 which contain samples obtained from patients having Alzheimer's disease. Thus, the claimed peptide (amino acid residues 2-18 of SEQ

ID NO:1) is differentially expressed between Alzheimer's disease and a normal (with respect to Alzheimer's disease), age-matched physiological state.

5. In order to further illustrate the point made in item 4, Applicants attach hereto a copy of Figure 1. The figure is entitled "DEAE 3 (Elution) AD vs. Age Matched AD(Control)" and represents Figure 1 as originally filed. This figure was produced by scanning the original photograph of the gel. No new matter has been added; this figure is simply a clearer copy of Figure 1 as originally filed and is provided to clarify the presence, absence and differential expression of the claimed biopolymer marker (amino acid residues 2-18 of SEQ ID NO:1). The gel shown in the attached figure does not represent new experimentation; the figure shows a clearer image of the original gel which was made at the time that the experiments described in the instant specification were first carried out.

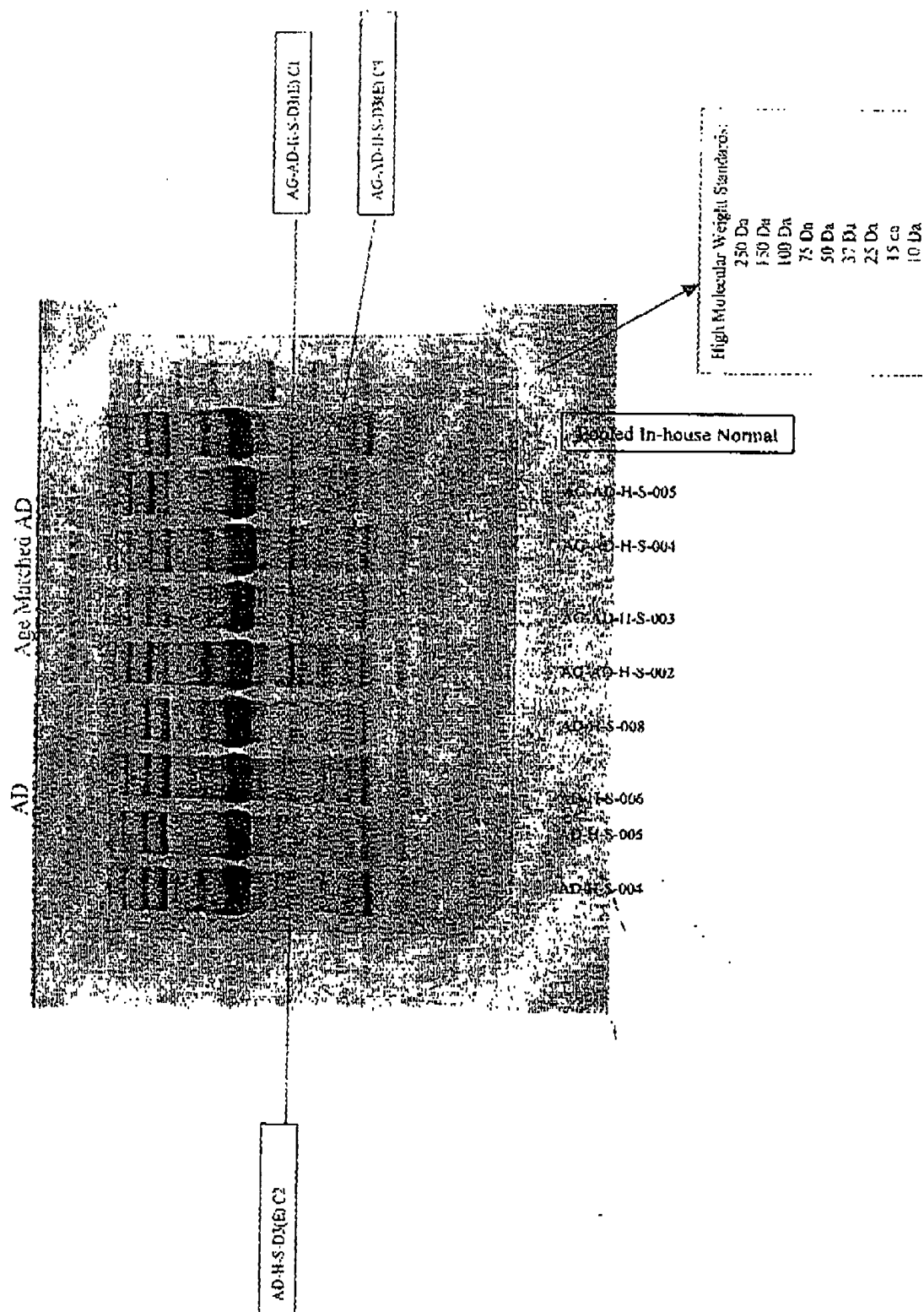
The undersigned declares that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the Application or any patent issuing thereon.

2/9/2005
Date

Ferris H. Lander
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DEAE 3(Elution) AD vs. Age Matched AD (Control)



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mark·er **Pronunciation Key** (mār'kər)
n.

1. One that marks or serves as a mark, as:
 - a. A bookmark.
 - b. A tombstone.
 - c. A milestone.
2. An implement, especially a felt-tipped pen, used for marking or writing.
3. One who marks objects, especially for industrial purposes.
4. One who grades student papers.
5. *Sports.*
 - a. A device, such as a line, stake, or flag, set on a playing field and showing the playing or scoring position.
 - b. A player who guards an opponent, as in soccer.
 - c. An official in certain court games, such as squash, who mainly judges whether the ball is out of play and whether a fault or let has occurred.
6. *Games.*
 - a. One that keeps score in various games.
 - b. A score in a game.

Dictionary.com/marker

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7. *Slang*. A written, signed promissory note.
8. A genetic marker.
9. *Medicine*. A physiological substance, such as human chorionic gonadotropin or alpha-fetoprotein, that when present in abnormal amounts in the serum may indicate the presence of disease, as that caused by a malignancy. Also called **biomarker**.
10. *Linguistics*. An element that indicates grammatical class or function; a derivational or inflectional morpheme.

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mark-er (mär'kər)

n.

1. One that marks or serves as a mark.
2. A physiological substance, such as human chorionic gonadotropin or alpha-fetoprotein, that may indicate disease when present in abnormal amounts in the serum, as that caused by a malignancy. Also called *biomarker*.
3. A genetic marker.

Source: *The American Heritage® Stedman's Medical Dictionary*

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Main Entry: **mark-er**

Pronunciation: 'mär-kər

Function: *noun*

1 : something that serves to identify, predict, or characterize <a surface *marker* on a cell that acts as an antigen> <erythema migrans ... is a distinctive *marker* for Lyme disease —Cecelia E. Holmes & Mary C. Massa>

2 : GENETIC MARKER called also *marker gene*

Source: *Merriam-Webster's Medical Dictionary*, © 2002 Merriam-Webster, Inc.**marker**

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n 1: some conspicuous object used to distinguish or mark something; "the buoys were markers for the channel" 2: a distinguishing symbol; "the owner's mark was on all the sheep" [syn: marking, mark] 3: a writing implement for making a mark

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marker

marker: in CancerWEB's On-line Medical Dictionary

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bi·o·mark·er **Pronunciation Key** (bī'ō-mär'ker)
n. Medicine

1. See marker.
2. A specific physical trait used to measure or indicate the effects or progress of a disease or condition: *Biomarkers of aging include thinning of the hair and diminished elasticity of the skin.*

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Source: *The American Heritage® Dictionary of the English Language, Fourth Edition*

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bi·o·mark·er (bī'ō-mär'ker)
n.

1. See marker.
2. A specific physical trait used to measure or indicate the effects or progress of a disease, illness, or condition.

<http://dictionary.reference.com/search?q=biomarker>

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Source: *The American Heritage® Stedman's Medical Dictionary*
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Main Entry: **bio·mark·er**

Pronunciation: 'bi-O-"mär-k&r

Function: *noun*

: a distinctive biological or biologically derived indicator (as a biochemical metabolite in the body) of a process, event, or condition (as aging or exposure to a toxic substance) <age-related *biomarkers* of disease and degenerative change —Janet Raloff>

Source: *Merriam-Webster's Medical Dictionary*, © 2002 Merriam-Webster, Inc.**biomarker**

biomarker: in CancerWEB's On-line Medical Dictionary

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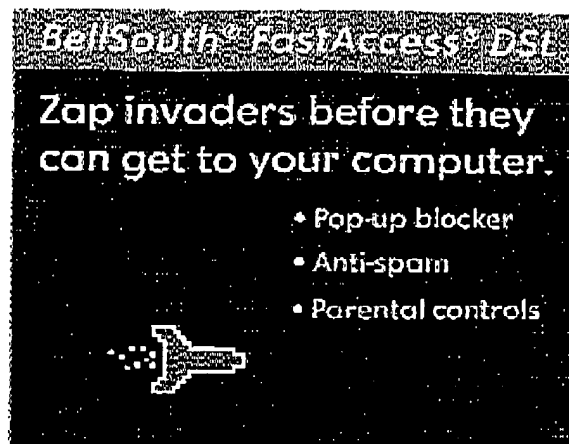
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